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REMARKS

This is responsive to the Office Action mailed on October 24, 2005. With this response, independent claims 1, 16, 34 and 36 are hereby amended. The application continues to include claims 1-9, 11-28, and 34-43.

The Office Action rejected claims 1-9, 11-28 and 34-43 under 35 U.S.C. 103(a) as being patentable over the Ogle et al. U.S. Patent 5,958,669 in view of the Yang et al. U.S. Patent 5,935,168 for reasons stated in previous Office Actions and for additional reasons stated in this Office Action.

Independent claims 1, 16, 34 and 36 have been amended to state that the bridges are not glutaraldehyde. It is believed that this amendment to the claims clearly distinguishes the claims over the art cited.

The Office Action states with reference to Yang et al. that "after reacting with glutaraldehyde as disclosed by Ogle et al., it would have been obvious to react with a diamine and then with additional glutaraldehyde as suggested by Yang et al. This will result in a diamine being a linker and the glutaraldehyde being a bridge. Additionally after initially cross-linking with glutaraldehyde some free aldehyde groups will remain that will react with the diamine and result in the glutaraldehyde being a linker and the diamine being a bridge. The aldehyde groups of glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde under certain conditions disclosed by Ogle et al. that control self-polymerizing. The amine groups of a diamine will not react with amine groups of another diamine. This will result in a bridge not reacting with another bridge."

It is respectfully submitted that these comments are a misreading of what Yang et al teaches or even suggests. Yang et al teaches providing a collagenous bioprosthesis which has been

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initially crosslinked with glutaraldehyde. Then the carboxyl groups in the collagen are converted to carboxyl moieties and then reacted with an amine which in effect replaces the previously existing carboxyl groups. (Column 3, Lines 55 -, Column 4, line 20).

Next an optional step is to once again immerse the bioprosthesis in glutaraldehyde.

As specifically stated in Yang et al: "If the non-carboxyl side groups formed on the collagen molecules are free of functional amino groups, this additional exposure to glutaraldehyde will not result in further cross-linking of the collagen molecules due to the absence of functional amine bonding sites with which the glutaraldehyde may react. However, if the non-carboxyl side groups formed on the collagen molecules do contain functional amino groups, this further exposure to glutaraldehyde will result in the formation of additional glutaraldehyde cross-linkages between such remaining free amino groups." (Col. 4, lines 23-32).

The Applicant believes that it is significant that Yang et al does not discuss a reaction of the glutaraldehyde used to initially cross-link the tissue with the second immersion of the bioprosthesis in glutaraldehyde. It must mean that the glutaraldehyde used to initially crosslink the tissue is no longer reactive with other glutaraldehyde. The above quote from column 4, lines 23-32 does not state that the second glutaraldehyde reacts with the collagen molecules (or initial glutaraldehyde) but only with the amino groups that have replaced the carboxyl groups in the collagen. Col. 3, lines 23-32 clearly states that without the amino group, there is no further cross-linking, and therefore, in the context of what Yang et al. discloses, there is no reaction between the initial glutaraldehyde with the second exposure to glutaraldehyde. The statements in the Office Action that initial glutaraldehyde has free aldehydes to react with the additional

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glutaraldehyde is simply contrary to this statement in Yang et al.

Furthermore, it is clear from the disclosure in Yang et al that the amine replaces the carboxyl group in the collagen tissue as a substitute functional group to avoid calcification of the tissue and then to be a reactive group upon further cross-linking (if desired) with a second immersion in glutaraldehyde. The suggestion in the Office Action that the diamine groups act as a bridge is a misreading of Yang et al. Yang et al specifically states that the purpose of the amino groups is to prevent further calcification of the bioprosthesis and to provide a further bonding sight for additional cross-linking with glutaraldehyde. If the amino groups were to act as bridges, then there would be no reactive sites for reaction in the second immersion of glutaraldehyde.

For the Office Action to state there are free aldehyde groups remaining after the initial cross-linking of the tissue is contrary to what is stated in Yang et al. To also state that Yang et al suggests or teaches that the amine groups form bridges is to ignore what is actually stated in Yang et al.. As stated in the MPEP, the prior art must be considered in its entirety, including disclosures that teach away from the claims. MPEP §2141.02. The Office cannot ignore what is actually disclosed in Yang et al.

It is believed that the amendment to the claims now clearly distinguishes the claims from the combination of references used to reject them. Reconsideration and allowance of all of the claims in the application are respectfully requested.

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The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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